**Remarks**

In view of the foregoing amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

By the above amendments, claim 4 has been cancelled and new claims 46 and 47 have been introduced (which are dependent on claims 1 and 13, respectively). Support for new claims 46 and 47 is found, for example, in claims 1 and 13. No new matter has been added.

Because claims 1 and 13 are allowable for the reasons noted below, rejoinder of the withdrawn method and composition claims is respectfully requested. New claims 46 and 47, dependent on claims 1 and 13, respectively, should also be joined with claims 1 and 13.

The rejection of claims 1, 3, and 4 under 35 U.S.C. § 102(b) as being anticipated by PCT International Patent Publication No. WO 2001/71042 A2 to Venter et al. ("Venter") as evidenced by U.S. Patent No. 6,355,610 B2 Chesebro et al. ("Chesebro") is respectfully traversed with regard to claims 1 and 3 and is obviated with regard to claim 4, as this claim has been cancelled.

Venter teaches nucleic acid arrays and detection kits that are based on portions of the *Drosophila melanogaster* genome. In particular, Venter discloses a large portion of the genomic sequence, predicted transcript sequences, and predicted amino acid sequences of *Drosophila melanogaster* which can be used to generate nucleic acid detection reagents and kits, such as nucleic acid arrays.

Chesebro teaches peptides that inhibit the conversion of protease sensitive prion protein (PrPsen) to the protease resistant isoform (PrPres). The peptides comprise discrete fragments of prion proteins and inhibit the *in vitro* conversion of PrPsen to PrPres in a cell-free system.

It is the position of the U.S. Patent and Trademark Office ("PTO") that claim 1 is anticipated by Venter, because the 216 amino acids of Venter's SEQ ID NO:20151 ("the Venter sequence") has within it seven amino acids (at positions 102-108) that match SEQ ID NO:5 of the present application. The PTO also states that because the Venter sequence contains these seven amino acids, it would be expected to bind to the prion peptide having the amino acid sequence of SEQ ID NO:1 of the present application. Chesebro is cited as

evidence because is discloses that SEQ ID NO:1 of the present application is comprised in the prion protein.

Applicants respectfully disagree. Contrary to the position taken by the PTO in the outstanding office action, there is no basis whatsoever for concluding that the Venter sequence would inherently bind to the prion peptide having the amino acid sequence of SEQ ID NO:1 of the present application. Further, the PTO's position is insufficient to meet the standard for inherency. The Federal Circuit explained the standard for determining inherency in Continental Can Co. USA, Inc. v. Monsanto Co. , 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1748 (Fed Cir. 1991) (quoting In re Oelrich , 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)) where it stated:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

The PTO has failed to meet the standard for inherency in the present application. In particular, the PTO's argument is devoid of any evidentiary support. Nowhere does Venter suggest that the disclosed sequence (SEQ ID NO:20151), which is one of over 43,000 sequences disclosed in Venter, binds to the prion peptide having the amino acid sequence of SEQ ID NO:1 of the present application. The only use that is ascribed to the sequences disclosed in Venter is for the detection of *Drosophila* genes. In addition, the PTO's position takes no account of the fact that the remainder of the Venter sequence will have an influence on whether or not the binding will occur, not least because the conformation of the lengthy Venter sequence could mean that the relevant seven amino acid sequence could be buried within the molecule and not exposed for interaction with the prion peptide.

In contrast to the PTO's position, independent claim 1 (and its dependent claim 3) requires: (1) that the ligand "is a peptide having an amino acid sequence selected from the group consisting of SEQ ID NOS:5-13," and (2) that the ligand "is capable of binding to a peptide having the amino acid sequence RYPGQ (SEQ ID NO:1)." Although the Venter sequence contains the seven amino acid sequence of SEQ ID NO:5 within its expanse, applicants disagree that this necessarily, or even likely, means that the Venter

sequence would be expected to bind to the prion peptide having the amino acid sequence of SEQ ID NO:1.

Accordingly, in the absence of any indication in Venter that the peptide of SEQ ID NO:20251 does in fact bind to SEQ ID NO:1 and in the absence of any evidence that the Venter sequence would inherently bind SEQ ID NO:1, Venter fails to disclose each and every limitation of claims 1 and 3. Chesebro fails to overcome this deficiency in Venter. Thus, the rejection of claims 1, 3, and 4 under 35 U.S.C. § 102(b) as being anticipated by Venter as evidenced by Chesebro is improper and should be withdrawn.

The rejection of claims 13 and 14 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,525,492 to Hill ("Hill") is respectfully traversed.

Hill teaches a process for HLA typing in polymorphic systems by polymerase chain reaction of the nucleic acids drawn to the alpha domain of the human leucocyte antigen (HLA) gene.

It is the PTO's position that Hill discloses a sequence that has six amino acids (SEQ ID NO:14) ("the Hill sequence") and comprises SEQ ID NO:116 of the present application. Thus, the PTO argues that Hills sequence would be expected to bind to the native form of the prion protein because Hills' sequence comprises SEQ ID NO:116 of the present application.

Applicants respectfully disagree. Contrary to the position taken by the PTO in the outstanding office action, there is no basis whatsoever for concluding that the Hill sequence would inherently bind to the native form of the prion protein. Further, as described above, this position is insufficient to meet the standard for inherency. In particular, the PTO's argument is devoid of any evidentiary support. Nowhere does Hill suggest that the disclosed sequence would bind to the native form of the prior protein. Indeed, the sequence cited by the PTO (Hill SEQ ID NO:14) is disclosed only as an amino acid sequence that is encoded by a particularly preferred probe (SEQ ID NO:12) (*See* col. 6, lines 14-21).

For substantially the same reasons as noted with respect to the preceding rejection, it cannot be concluded that the sequence of Hill would necessarily (or even likely) exhibit the binding activity as recited in claims 13 and 14 and, therefore, Hill fails to teach each and every aspect of claims 13 and 14. Thus, the rejection of claims 13 and 14 under 35 U.S.C. § 102(b) as being anticipated by Hill is improper and should be withdrawn.

The rejection of claim 42 under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of U.S. Patent No. 5,750,361 to Prusiner et al. ("Prusiner") is respectfully traversed.

Prusiner teaches methods for screening compounds able to inhibit or decrease the binding of prion protein peptides to cellular prion protein and methods for assaying the scrapie isoform of prion protein.

Hill is cited as teaching a prion protein binding ligand comprising SEQ ID NO:116 of the present invention. Prusiner is cited as teaching prion protein peptides immobilized to a membrane solid support for detection of anti-prion antibodies. Thus, the PTO argues that it would have been obvious to attach prion protein binding ligands to a solid support in order to facilitate the detection of prion proteins in a detection assay.

Applicants respectfully disagree. As noted above, Hill is concerned with a process for amplifying nucleic acid sequences that encode a human leucocyte antigen (HLA). There is no disclosure of any usefulness of the sequences disclosed for the binding of any specific proteins. Moreover, as described above, there is no basis whatsoever for concluding that the Hill sequence cited by the PTO would inherently bind to the native form of the prion protein.

Prusiner fails to overcome the above-noted deficiencies of Hill.

Thus, for these reasons, the rejection of claim 42 under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of Prusiner is improper and should be withdrawn.

The rejection of claims 36, 37, and 45 under 35 U.S.C. § 103(a) as being unpatentable over Venter in view of Prusiner is respectfully traversed.

Venter is cited as disclosing a prion protein biding ligand comprising SEQ ID NO:5 of the present invention. Prusiner is cited for teaching prion proteins immobilized to a membrane solid support for detection of anti-prion antibodies. Thus, the PTO argues that it would have been obvious to attach prion protein binding ligands to a solid support in order to use the prior protein binding ligands for detection of prion proteins in a sample.

Applicants respectfully disagree. As noted above, Venter discloses sequencing of the genome of *D. melanogaster*, and the information is given in the form of genomic sequences, transcript sequences, and protein sequences that can be used to generate nucleic acid detection reagents and kits such as nucleic acid arrays. The only use that is ascribed to the sequences disclosed in Venter is for the detection of *Drosophila* genes.

Moreover, there is no basis whatsoever for concluding that the Venter sequence cited by the PTO would inherently bind to the prion peptide having the amino acid sequence of SEQ ID NO:1 of the present application.

Prusiner fails to overcome the above-noted deficiencies of Venter.

Accordingly, the rejection based on Venter and Prusiner is improper and should be withdrawn.

The provisional nonstatutory obviousness-type double patenting rejection of claims 1, 3, 4, 13, 14, 42, and 45 as being unpatentable over claims 1, 3, 4, 13-19, 36-41, 44, and 47-58 of copending U.S. Patent Application No. 12/035,917, is noted. However, Applicants respectfully request that any requirement for a terminal disclaimer be held in abeyance, pursuant to Manual of Patent Examining Procedure § 804, until the claims of one of the applications are allowed.

The double patenting warning is obviated in view of the cancellation of claim 45.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: September 10, 2009

/Georgia Evans/
Georgia Evans
Registration No. 44,597

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604
Telephone: (585) 263-1000
Facsimile: (585) 263-1600